



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/184,043	11/02/98	HORNAUER	P564-8023

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NIKAIDO MARMELESTEIN MURRAY & ORAM
METROPOLITAN SQUARE 655 FIFTEENTH
STREET NW SUITE330-G STREET LOBBY
WASHINGTON DC 20005-5701

EXAMINER

CEPERLEY, M

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/184,043

Applicant(s)

HORNAUER et al

Examiner

Mary E. Ceperley

Group Art Unit

1641



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-12, 14-26, and 28-42 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-12, 14-26, and 28-42 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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1. The following problems are noted.

- a. In claim 22, there is no "r" variable present in formula (II).
- b. The formula (III) of claim 23 contains a "P_r" moiety but the variable defined below it is "P".
- c. In claim 31, the term "M" appears in the formula (IV) but the variable "m" is defined below the formula.
- d. Throughout the specification and claims (with the exception of claim 23), the group "AO" is defined as "a C₂-C₃-alkylene oxide group", e.g. ethylene oxide or propylene oxide. Repeat units of alkylene oxide are conventionally described using a designation such as "(AO)_n" [i.e. the "(AO)" unit being repeated "n" number of times]. However, the term "(AO_n)" as it is used in the specification and claims is inconsistent with this designation since the term "(AO_n)" would indicate that "n" number of repeating oxygen atoms are present rather "n" number of "(AO)" units.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method for detecting an analyte using a solid phase to which is attached an analyte-specific solid phase reactant and an analyte-unspecific biomolecule coupled to a polyalkylene oxide.
- II. Claims 8-12, 39 and 40, drawn to PEO/PPO conjugates with a member of a specific binding pair, solid phases coated with the conjugates, a method of

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reducing non-specific binding using the conjugates and a kit containing the conjugates.

III. Claims 14-21, drawn to a method of detecting an analyte using a solid phase on which is immobilized a “modified solid phase reactant” coupled to an alkylene oxide.

IV. Claims 22-26, 31-34, 41, and 42 drawn to conjugates of a) a biomolecule and polyalkylene oxide, a method for their use and a kit containing them; b) conjugates of a) with a member of a specific binding pair and a kit containing them; and c) conjugates of a) linked to a labeling group.

V. Claims 35-38, drawn to methods for reducing non-specific binding and a reagent kit containing the same.

VI. Claims 28-30, drawn to a method for detecting an analyte using a solid phase containing a specific binding pair member and a test reagent containing a PEO/PPO modified analyte-specific reactant.

3. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the distinct methods of use have different modes of operation and use compositions comprised of diverse components. For example, the method of Group I uses “*an analyte-unspecific biomolecule* which is coupled to a poly(C₂-C₃)-alkylene oxide” while the method of Group III requires that the

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“modified solid phase reactant” be “coupled to a poly(C₂-C₃)-alkylene oxide”. Likewise, the method of Group V requires the use of a reactant (“at least one reagent which contains a *substance* coupled to a poly(C₂-C₃)-alkylene oxide”) which is different than the conjugate of Group II (“P_r[-(AO_n)T]_m”).

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter requiring diverse fields of search in both the patent and technical literature (e.g. Group I, class 436; Group II, class 435; Group IV, class 530), restriction for examination purposes as indicated is proper.

5. Applicants are advised that the claims, *as written*, are directed to distinct inventions as set forth above. However, claims presented in a divisional application may still be subject to an obviousness-type double patenting rejection if the claim language *is changed* such that the inventions overlap in subject matter and a line of demarcation is not maintained between the applications.

6. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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7. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

8. **In accordance with the duty to disclose, applicants are requested to provide an Information Statement (MPEP 609).**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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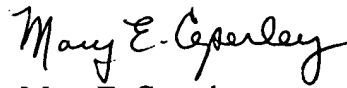
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February 25, 2000

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A handwritten signature in cursive script, reading "Mary E. Ceperley".

Mary E. Ceperley
Primary Examiner
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